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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,046	07/21/2005	Lisa Marie Shewchuk	PU4804USW	7149
23347 7590 12/24/2008 GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398				
EXAMINER STEADMAN, DAVID J				
ART UNIT 1656		PAPER NUMBER		
NOTIFICATION DATE 12/24/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary

Application No.

10/543,046

Applicant(s)

SHEWCHUK ET AL.

Examiner

David J. Steadman

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 6 and 10-14 is/are pending in the application.
4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 4, 6 and 10 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date 9/29/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of the Application

- [1] Claims 4, 6, and 10-14 are pending in the application.
- [2] Applicant's amendment to the claims, filed on 9/29/08, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicant's amendment to the specification, filed on 9/29/08, is acknowledged.
- [4] Receipt of a substitute Declaration under 37 CFR 1.63, filed on 9/29/08, is acknowledged.
- [5] Receipt of an information disclosure statement, filed on 9/29/08, is acknowledged.
- [6] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, all filed on 9/29/08, is acknowledged.
- [7] Applicant's arguments filed on 9/29/08 in response to the Office action mailed on 5/27/08 have been fully considered and are deemed to be persuasive to overcome at least one of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [8] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Election/Restriction

[9] Applicant continues to traverse the requirement for a species election, the traversal is on the ground(s) that “there is a technical relationship between species i-xxxi because they are all potential sites of interaction between the ErbB4 kinase domain and a compound that is a potential inhibitor. Accordingly, these species are linked to form a general inventive concept and should be examined together”.

As noted in the prior Office action, this is not found persuasive because according to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The species of i to xxxi do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of species i to xxxi is a method of ErbB4 inhibitor design, which is shown by the combination of Groenen, Cohen, Traxler, Plowman-1, and Plowman-2 in view of the legal rationale of *In re Gulack*, to lack novelty or inventive step because the combination teaches a method of ErbB4 inhibitor design for reasons set forth below and does not make it a contribution over the prior art.

[10] Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/14/08.

[11] Claims 6 and 10 are being examined only to the extent the claims read on the elected species.

Information Disclosure Statement

[12] The reference cited in the IDS filed on 9/29/08 has been considered by the examiner. A copy of Form PTO/SB/08 attached to the instant Office action.

Oath/Declaration

[13] The objection to the Declaration filed under 37 CFR 1.63 is withdrawn in view of the substitute Declaration under 37 CFR 1.63, filed on 9/29/08.

Specification/Informalities

[14] In order to perfect the requirements for a sequence listing, applicant is required to submit an amendment to the specification directing entry of the substitute sequence listing paper copy filed on 9/29/08 into the application.

Claim Rejections - 35 USC § 112, Second Paragraph

[15] The rejection of claims 4, 6, and 10 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "represents" is withdrawn in view of the amendment to claims 4, 6, and 10 to delete the term at issue.

[16] The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "evaluating compounds..." in step (b) is withdrawn upon

further consideration of the noted phrase and the specification's disclosure at p. 33, providing exemplary descriptions of "evaluate".

Claim Rejections - 35 USC § 112, First Paragraph

[17] The written description and scope of enablement rejections of claim(s) 4, 6, and 10 under 35 U.S.C. 112, first paragraph, are withdrawn in view of the instant claim amendment to delete the phrase "represents" such that that 3D computer model of ErbB4 is limited to having the structural coordinates of Table 2.

Claim Rejections - 35 USC § 103

[18] The rejection of claim(s) 4, 6, and 10 under 35 U.S.C. 103(a) as being unpatentable over Groenen et al. (*Biochemistry* 36:3826-3836, 1997; "Groenen") in view of Cohen et al. (*J. Med. Chem.* 33:883-894, 1990; "Cohen"), Traxler et al. (*Pharmacol. Ther.* 82:195-206, 1999; "Traxler"), Plowman et al. (*PNAS* 90:1746-1750, 1993; "Plowman-1"), and Plowman (US Patent 5,804,396; "Plowman-2") is withdrawn in view of the instant claim amendment to delete the phrase "represents" such that that 3D computer model of ErbB4 is limited to having the structural coordinates of Table 2. The combination of references does not appear to teach or suggest the structural coordinates of Table 2.

[19] The rejection of claim(s) 4, 6, and 10 under 35 U.S.C. 103(a) as being unpatentable over Groenen in view of Cohen, Traxler, Plowman-1, and Plowman-2 and

the legal precedent of *In re Gulack* 217 USPQ 401 (Fed. Cir. 1983) is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See paragraph 15 beginning at p. 17 of the Office action mailed on 5/27/08.

RESPONSE TO ARGUMENT: Beginning at p. 10 of the instant remarks, applicant argues the Table 2 structural coordinates are "integral to the step of modeling", wherein the result of the claimed methods is dependent upon the particular structural coordinates and thus are functionally related to a computer upon which they are stored.

Applicant's argument is not found persuasive. Initially it is noted that there appears to be no dispute that – with the exception of the structural coordinate data of Table 2 – the prior art references combine to teach all claim limitations. Also, there is no dispute that the structural coordinate data of Table 2 is novel or unobvious over the prior art of record.

The examiner maintains the position that in view of the holding in *In re Gulack*, the structure coordinate data of Table 2 is non-functional descriptive material and therefore in view of the legal precedent of *In re Gulack*, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.

According to *Gulack*, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight...[T]he critical question is whether there exists any

new and unobvious functional relationship between the printed matter and the substrate." See also MPEP 2112.01.III. The recited structural coordinate data appear to be stored on a computer, intended merely as input for a known computer algorithm that, in combination with the elements of the computer, generates a three-dimensional protein structure. In this case, the computer would appear to function in the same manner regardless of whether or not the structural coordinate data were stored on the computer. In other words, the data do not appear to affect how the computer performs or functions. See Cases 6 and 7 of "Annex 3: Comments of the USPTO" of the "Trilateral Project WM4, Comparative studies in new technologies (biotechnology, business methods, etc.), Report on comparative study on protein 3-dimensional (3-D) structure related claims", Vienna, Austria November 4-8, 2002, pp. 69-76.

According to MPEP 2106.01, "'functional descriptive material' consists of data structures and computer programs which impart functionality when employed as a computer component". (The definition of 'data structure' is 'a physical or logical relationship among data elements, designed to support specific data manipulation functions'" (emphasis added) and "'Nonfunctional descriptive material' includes but is not limited to music, literary works, and a compilation or mere arrangement of data". In this case, the method involves using a computer and a known algorithm (see, e.g., pp. 31-32 of the specification) to transform the data into a 3-D macromolecular structure. The structural coordinates appear to be an arrangement of data, defining the Cartesian coordinates of atoms of the ErbB4 protein, and do not appear to affect how the computer performs or functions. The computer would appear to function in the same

way regardless of whether or not the data is stored in a computer's machine-readable data storage medium, in the same way as music or a literary work stored on a computer would not affect its function. Although applicant asserts the result of the method is dependent upon the atomic coordinates of Table 2, one of ordinary skill in the art would similarly expect the audio or visual "result" to be dependent on the music or literary work stored on a computer, however, MPEP 2106.01 makes clear that "nonfunctional descriptive material" includes music and literary works.

Contrast the atomic coordinate data with the data structure of *Lowry*, which, according to MPEP 2106.01, when stored on a computer readable medium, increases computer efficiency. As noted above, there is no evidence of record that the recited structural data interact with other computer hardware or software to affect the efficiency or accuracy or any other characteristic of computer processing. Consequently, for reasons of record and the reasons set forth above, the structural coordinate data of Table 2 has not been accorded patentable weight.

At least for the reasons of record and the reasons set forth above, the examiner maintains the position that the claimed invention, which differs from the prior art by only the recitation of non-functional descriptive material, would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

[20] Status of the claims:

Claims 4, 6, and 10-14 are pending.

Claims 11-14 are withdrawn from consideration.

Claims 4, 6, and 10 are rejected.

No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
Primary Examiner, Art Unit 1656